

**Next Generation Uric Acid (k102568) Response
Attachment H – 510(k) Summary**

**Architect Uric Acid
510(k) Summary (Summary of Safety and Effectiveness)**

MAY - 6 2011

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name:

Linda Morris, Sr. Regulatory Specialist
Regulatory Affairs
Abbott Laboratories Diagnostics Division
Dept. 2471
1921 Hurd Drive
Irving, TX 75038

Device Name:

Reagents:

Classification Name: Acid, Uric, Uricase (U.V.)
Trade Name: Architect Uric Acid
Common Name: Uric Acid
Governing Regulation: 862.1775
Device Classification: Class I
Classification Panel: Clinical Chemistry
Product Code: KNK

Legally marketed device to which equivalency is claimed:

Abbott Uric Acid Assay (K981766)

Intended Use of Device:

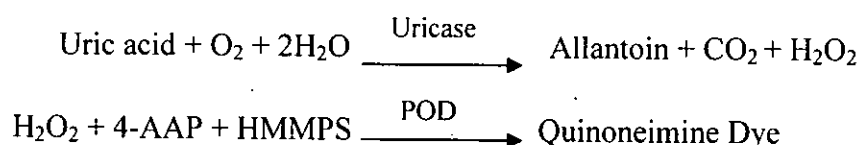
The Architect Uric Acid assay is used for the quantitation of uric acid in human serum, plasma, or urine.

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Description of Device:

The Uric Acid assay is an in vitro diagnostic assay for use on the ARCHITECT c8000 System for the quantitative determination of uric acid in human serum, plasma, or urine using a uricase methodology. The Uric Acid assay is a two-part reaction. Uric acid is oxidized to allantoin by uricase with the production of hydrogen peroxide (H₂O₂). The H₂O₂ reacts with 4-aminoantipyrine (4-AAP) and N-(3-sulfoethyl)-3-methoxy-5-methylalanine (HMMPS) in the presence of peroxidase (POD) to yield a quinoneimine dye. The resulting change in absorbance at 604 nm is proportional to the uric acid concentration in the sample.

The two-part (R1/R2) configuration of this assay allows reduction of interference from ascorbic acid by inclusion of ascorbic oxidase in the R1 portion of the assay.



Comparison of Technological Characteristics:

The Uric Acid assay uses a uricase methodology for the quantitative determination of uric acid in human serum, plasma, or urine. The Abbott On-Market Uric Acid assay also uses a uricase methodology for the quantitative measurement of uric acid in human serum, plasma, or urine.

Summary of Non-Clinical Performance:

The Uric Acid assay is substantially equivalent to the Abbott On-Market Uric Acid assay. Both assays yield similar performance characteristics as demonstrated in the non-clinical performance data in this 510(k) submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
Diagnostics Division
c/o Linda K. Morris
Sr. Regulatory Specialist
1921 Hurd Drive
Irving, TX 75038-4313

MAY 6 2011

Re: k102568
Trade Name: ARCHITECT Uric Acid Assay
Regulation Number: CFR 862.1775
Regulation Name: Uric acid test system
Regulatory Class: Class II
Product Codes: KNK
Dated: April 26, 2011
Received: April 27, 2011

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

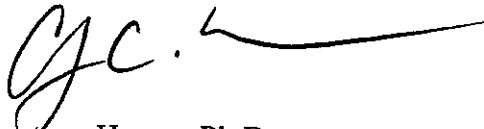
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CH', followed by a long horizontal line extending to the right.

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Next Generation Uric Acid (k102568) Response
Attachment G – Indications for Use Form

Uric Acid

Indication(s) for Use Form

510(k) Number (if known): K102568

Device Name: ARCHITECT Uric Acid

Indication(s) for Use:

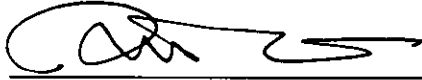
The ARCHITECT Uric Acid test system is a device intended to measure uric acid in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102568